Date of Revision: January 5, 2024



## COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006

# SECTION 1: Identification of the substance/mixture and of the company/ undertaking

- · 1.1 Product identifier
- Trade name: Neelicert FD & C Blue 1
- · CAS Number:

3844-45-9

· EC number:

223-339-8

- Registration number 01-2120740569-45-0008
- 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Life cycle stages
- Use at industrial Sites IS
- PW Widespread use by professional workers
- Consumer use
- · Sector of Use
- SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU4 Manufacture of food products
- SU8 Manufacture of bulk, large-scale chemicals (including petroleum products)
- SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
- SU21 Consumer uses: Private households / general public / consumers
- SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- Product category
  - PC 1 Adhesives, sealants.
- PC8 Biocidal products.
- PC 9a Coatings and paints, thinners, paint removes.
- PC9b Fillers, putties, plasters, modelling clay.
- PC 9c Finger paints.
- PC13 Fuels.
- PC 18 Ink and toners.
- PC 21 Laboratory chemicals.
- PC 23 Leather treatment products.
- PC 24 Lubricants, greases, release products.
- PC 25 Metal working fluids.
- PC 26 Paper and board treatment products.
- PC 24 Lubricants, greases, release products
- PC 25 Metal working fluids.
- PC27 Plant protection products.
- PC28 Perfumes, fragrances. PC29 Pharmaceuticals.
- PC31 Polishes and wax blends.
- PC 34 Textile dyes, and impregnating products.
- PC 35 Washing and cleaning products.
- PC 39 Cosmetics, personal care products.
- PC 0: Other. Colouring agents, pigments.



### · Process category

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition PROC4 Chemical production where opportunity for exposure arises

PROC5 Mixing or blending in batch processes

PROC7 Industrial spraying

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities

PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

PROC11 Nonindustrial spraying

PROC14 Tabletting, compression, extrusion, pelletisation, granulation

PROC15 Use as laboratory reagent

PROC28 Manual maintenance (cleaning and repair) of machinery

### · Environmental release category

ERC1 Manufacture of the substance

ERC3 Formulation into solid matrix

ERC5 Use at industrial site leading to inclusion into/onto article

ERC6b Use of reactive processing aid at industrial site (no inclusion into or onto article) ERC7 Use of functional fluid at industrial site

ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)

ERC8c Widespread use leading to inclusion into/onto article (indoor)

ERC4 Use of non-reactive processing aid at industrial site (no inclusion into or onto article).

#### · Article category

AC1 Vehicles

AC2 Machinery, mechanical appliances, electrical/electronic articles

AC4 Stone, plaster, cement, glass, and ceramic articles

AC5 Fabrics, textiles, and apparel

AC6 Leather articles

AC8 Paper articles

AC10 Rubber articles

AC30 Other articles with intended release of substances

#### · Application of the substance / the mixture

It is a colorant for foods and other substances to induce a color change. manufacturing of the substance.

### · 1.3 Details of the supplier of the safety data sheet

· Windy Point Soap Making Supplies Inc.

14, 6125-12th Street SE

Calgary, AB T2H 2K1

· 587-318-6678



· 1.4 Emergency telephone number:

M/s Neelikon Food Dyes & Chemicals Ltd., D-8,Everest,5th Floor,Pdt.M.M.Marg,Tardeo Circle, Mumbai 34,India Tel.: 00 91 22 66626 874, Mobile

No.:00 91 9970004002 Kind Attn. Mr. Rajeev Mathyal

## SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

The substance is not classified, according to the CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Not applicable
- · Hazard pictograms No pictogram
- Signal word No signal word
- · Hazard statements Not applicable
- **2.3 Other hazards** The substance has no endocrine-disrupting properties according to Regulation (EU) 2017/2100
- Results of PBT and vPvB assessment
- · **PBT**: The substance is not PBT.
- · vPvB: The substance is not vPvB.

# SECTION 3: Composition/information on ingredients

- · 3.1 Chemical characterisation: Substances
- · CAS No. Description

3844-45-9 Neelicert FD & C Blue 1

- · Identification number(s)
- **EC number:** 223-339-8
- · Additional information:

Molecular Formula: C37H34Na2N2O9S3

Molecular Weight: 792.86 g/mol

Synonyms: C.I. Acid Blue 9, FD&C Blue No.1, Acid Blue

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IUPAC name: dihydrogen (ethyl)[4-[4-[ethyl(3-sulphonatobenzyl)]amino]-2'-sulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)ammonium, disodium salt

· **SVHC** the substance is not listed in current SVHC list.

## SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- General information:

First aid personnel should pay attention to their own safety.

Move out of dangerous area

· After inhalation:

After inhalation of greater quantities of dust, take affected person to fresh air.

Encourage patient to blow nose to ensure clear passage of breathing.

After skin contact:

Generally, the product does not irritate the skin.

In case of contact with skin, clean with soap and water.

After eye contact:

Check and remove contact lenses, if present and easy to do.

Eyelids should be held away from the eyeball to ensure thorough rinsing.

Rinse opened eye for several minutes under running water.

After swallowing:

Do not induce vomiting

Drink plenty of water.

- **Information for doctor:** Treat symptomatically and supportively.
- 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## SECTION 5: Firefighting measures

- 5.1 Extinguishing media
- Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

Use water spray, Class A foam, dry chemical.

For safety reasons unsuitable extinguishing agents:

water with full jet.

Quick-acting BC powder extinguisher, Quick-acting CO2 extinguisher.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Nitrogen oxides (NOx)



Carbon monoxide (CO)

Sulphur dioxide (SO2)

Carbon dioxide (CO2)

### · 5.3 Advice for firefighters

Use standard fire fighting procedures.

If safe to do so, remove containers from path of fire.

Use water delivered as a fine spray to control fire and cool adjacent area.

Protective equipment:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus.

## SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Avoid formation of dust.

· 6.2 Environmental precautions:

Do not discharge into drains, water courses or onto the ground.

Inform respective authorities in case of seepage into water course or sewage system.

· 6.3 Methods and material for containment and cleaning up:

Prevent further leakage or spillage if safe to do so. Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal. Do not let product enter drains.

· 6.4 Reference to other sections

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

See Section 7 for information on safe handling.

# **SECTION 7: Handling and storage**

### · 7.1 Precautions for safe handling

Any unavoidable deposit of dust must be regularly removed.

Avoid contact with eyes.

Follow good manufacturing practices for housekeeping and personal hygiene.

Provide appropriate exhaust ventilation at places where dust is formed.

· Information about fire - and explosion protection:

Normal measures for preventive fire protection.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage.
- Requirements to be met by storerooms and receptacles:

Check all containers are clearly labelled and free from leaks.

Store in ambient temperature and dry Place. Keep container close while not in use.



· Information about storage in one common storage facility:

keep away from food materials

Store away from reducing agents.

Store away from oxidising agents.

· Further information about storage conditions:

Check regularly for leaks.

To maintain product quality, do not store in heat or direct sunlight.

Keep container tightly sealed.

· 7.3 Specific end use(s) No further relevant information available.

## SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- Ingredients with limit values that require monitoring at the workplace: Not required.
- · DNELs

Hazard conclusions for Workers:

Inhalation

Systemic effects - Long-term: Hazard unknown (no further information necessary as no exposure expected)

Systemic effects - Short-term: Hazard unknown (no further information necessary as no exposure expected)

Local effects - Long-term: Hazard unknown (no further information necessary as no exposure expected)

Local effects - Short-term: Hazard unknown (no further information necessary as no exposure expected)

Dermal

Systemic effects - Long-term: No hazard identified Systemic effects - Short-term: No hazard identified Local effects - Long-term: No hazard identified Local effects - Short-term: No hazard identified

Hazard conclusions for the general population:

Oral

Systemic effects - Long-term: 6 mg/kg bw/day Systemic effects - Short-term: No hazard identified

Dermal

Systemic effects - Long-term: No hazard identified Systemic effects - Short-term: No hazard identified Local effects - Long-term: No hazard identified Local effects - Short-term: No hazard identified

Inhalation

Systemic effects - Long-term: Hazard unknown (no further information necessary as no

exposure expected)



Systemic effects - Short-term: Hazard unknown (no further information necessary as no exposure expected)

Local effects - Long-term: Hazard unknown (no further information necessary as no exposure expected)

Local effects - Short-term: Hazard unknown (no further information necessary as no exposure expected)

PNECs

Freshwater: No hazard identified

Intermittent releases (freshwater): No hazard identified

Marine water: No hazard identified

Intermittent releases (marine water): No hazard identified Sewage treatment plant (STP): No hazard identified

Sediment (freshwater): No data available Sediment (marine water): No data available

Air: No hazard identified Soil: No hazard identified

Hazard for Predators (Secondary poisoning): No potential for bioaccumulation

#### · 8.2 Exposure controls

- Personal protective equipment:
- · General protective and hygienic measures:

Good personal hygiene practices should be followed.

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Keep away from foodstuffs, beverages and feed.

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection:

Good ventilation is desirable and respiratory protection during dust formation.

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

### · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

### Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.



· Eye protection:



Tightly sealed goggles

Tightly fitting safety goggles (splash goggles) (e.g. EN 166) Body protection: Standard work wear and safety boots for normal handling and use.

9.1 Information on basic physical and ch	emical properties
General Information Appearance:	Solid
Form:	Powder
· Colour:	Reddish Blue
Odour:	Characteristic
pH-value:	4 – 6.5( 1% Solution in Water )
Change in condition	
Melting point/freezing point:	Not applicable.
Initial boiling point and boiling range:	Not applicable.
Flash point:	The flash point is only a relevant property for
	liquids; thus, it does not need to be done for
	substances that are solids or gases at room
	temperature.
Flammability (solid, gas):	Product is not flammable.
Decomposition temperature:	> 281 °C
Auto-ignition temperature:	Not self-ignited up to 400 degree C
Explosive properties:	Product does not present an explosion hazar
Explosion limits:	
Upper:	
Oxidising properties	Non oxidising
Vapour pressure:	Vapour pressure value could not be
	determined as the substance decomposes.
Bulk Density:	0.6-0.8 g/cm³(After tapping)



· Solubility in / Miscibility with

water at 23 °C: 135.0 g/l

· Partition coefficient: n-octanol/water at 23

°C: <-6.4 log POW (OECD TG 105)

Viscosity:

**Dynamic:** Not applicable.

• 9.2 Other information No further relevant information available.

## SECTION 10: Stability and reactivity

- · 10.1 Reactivity No hazardous reactions if stored and handled as prescribed/indicated.
- · 10.2 Chemical stability Stable under normal conditions.
- Thermal decomposition / conditions to be avoided:

No thermal effect on test substance found below 150°C thus the test substance is considered stable at room temperature.

10.3 Possibility of hazardous reactions

The product may contain explosive fine dust, or such dust may be produced by abrasion during transport or product transfer.

The product is stable if stored and handled as prescribed/indicated.

- 10.4 Conditions to avoid Heat, flame, and other sources of ignition
- · 10.5 Incompatible materials:

Oxidizing agents

Reducing agent.

· 10.6 Hazardous decomposition products:

Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides, Sodium oxides

# SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- Acute toxicity Based on available data; the classification criteria are not met.
- · LD/LC50 values relevant for classification:

Oral LD50 >2000 mg/kg bw (rat) (OECD Guideline 401)

- Primary irritant effect:
- · Skin corrosion/irritation

Skin irritation occurred in 40 of 207 volunteers following 48-hour covered application of test substance. Only a summary and not the full report was available for evaluation. Thus it is insufficient to classify the substance as skin irritant.



### · Serious eye damage/irritation

Transient eye irritation occurred in rabbits treated (over a 4-week period) with 40 x 0.2 ml applications of a 10% aqueous suspension of either Brilliant Blue or its lake. Only a summary, and not the full report, was available for evaluation. Thus substance can not be classified as eye irritant.

### · Respiratory or skin sensitisation

The stimulation indices were less than 3 at all tested concentrations, hence an EC3 value could not be calculated, and the test substance was classified as non-sensitizing in the vehicles tested.

### · Additional toxicological information:

### · Toxicokinetics, metabolism and distribution

The substance is taken up by the body after ingestion at a very low extent and only after high doses (eg 1900 mg/kg bw) as indicated by green coloration of the urine of experimental animals in the acute toxicity study. It is eliminated mainly via the bile and to a lesser extent via the urine. At low doses with 14-C-labelled material, absorption is generally below the limit of detection.

High oral doses cause diarrhea as the presence of an ironic, water-soluble substance results in water retention in the large intestine.

### · Repeated dose toxicity

The NOAEL for chronic oral exposure in rats is 631 mg/kg bw. Therefore, no serious irreversible effects are present at dose levels of less than 50 mg/kg bw upon subchronic exposure. As a result, the substance is not considered to be classified for repeated dose toxicity

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
The substance is not carcinogenic non-mutagenic and nontoxic for reproduction.

### · Germ cell mutagenicity

CAS 3844-45-9 was tested in a valid GLP compliant Ames test following OECD guideline 471 (CIT 2005). Tester strains Salmonella typhimurium TA 98. 100, 1535, 1537 and 102 as well as E. coli WP2 uvrA were used. Water was used as a vehicle. A moderate to marked coloration was observed in the Petri plates when scoring the revertants at all dose-levels. This coloration made the plates unreadable at dose-levels > 1 mg/plate. No noteworthy toxicity was noted towards the strains used, with and without S9 mix. No precipitate was observed in the Petri plates when scoring the revertants at all dose-levels. No increase in the mutant frequency was observed.

### · Carcinogenicity

No carcinogenic effects were observed at dose levels exceeding the limit dose in life-long feeding studies in rats and mice. As a result, the substance is not considered to be classified for carcinogenicity

## · Reproductive toxicity

NOAEL: 1072 mg/kg bw/day

the test substance was tested for OECD Guideline 443 (Extended One-Generation Reproductive Toxicity Study) in rats. Examinations on offspring performed after 12 months and at the end of lifetime exposure. The F1 generation developed normally during their lifetime. In females, exposure of 2% in the diet caused effects on body weight gain and survival rate after 90 - 102 weeks of treatment, males were not affected. F1 animals showed no histopathology findings in the gonads or other organs.



· STOT-single exposure No further relevant information available.

## · STOT-repeated exposure

Dose descriptor groups:

NOAEL: ≥ 2 (actual dose: 1000 mg/kg bw) & 1 (630 mg/kg bw) other: % in the diet

Mortality: no mortality observed

Body weight and weight changes: effects observed, treatment-related

Description (incidence and severity): high dose group females starting week 102.

Food consumption and compound intake (if feeding study): effects observed, treatment-related.

Description (incidence and severity): slightly increased at the high dose group 15% reduction in body weight (body weight affected after week 102).

After week 90, mean body weights of the 2.0% females began a steady downward trend that was statistically significant (P < 0.01) from week 102 until the end of the study.

- · Aspiration hazard No further relevant information available.
- 11.2 Information on other hazards
- •11.2.1 Endocrine disrupting properties: The substance has no endocrine-disrupting properties according to Regulation (EU) 2017/2100
- 11.2.2 Information on other hazard: No further information is available.

## SECTION 12: Ecological information

· 12.1 Toxicity	
· Aquatic toxicity:	
EC50 (48 h) (static)	>100 mg/L (Daphnia magna) (EU Method C.2)
LC50 (96 h)	>220 - <460 mg/L (Leuciscus idus (Fish, fresh water)) (according to DIN 38412 part 11)
EC50	> 100 mg/L (Chlorella vulgaris) (OECD Guideline 201)

### 12.2 Persistence and degradability

The test substance is not readily biodegradable

A GLP guideline study according to OECD 301B has been conducted. Activated sludge from a municipal sewage plant was exposed for 28 d and the CO2-Evolution was determined. After 28 d the biodegradation was determined to be < 10%. Therefore, the test substance is not readily biodegradable.

### · 12.3 Bioaccumulative potential

No further information is available.



- · 12.4 Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Assessment by list): slightly hazardous for water Must not reach sewage water or drainage ditch undiluted or unnaturalized.

Do not allow product to reach ground water, water course or sewage system.

- 12.5 Results of PBT and vPvB assessment
- · **PBT**: The substance is not PBT.
- · **vPvB**: The substance is not vPvB.
- **12.6 Endocrine disrupting properties**: The substance has no endocrine-disrupting properties according to Regulation (EU) 2017/2100
- · 12.7 Other adverse effect: No further information is available.

## SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must be sent to a suitable incineration plant, observing local regulations.

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

- Uncleaned packaging:
- Recommendation:

Dispose of packaging according to regulations on the disposal of packaging.

14.1 UN-Number		
ADR, ADN, IMDG, IATA	Not regulated	
14.2 UN proper shipping name		
ADR, ADN, IMDG, İATA	Not regulated	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	Not regulated	
14.4 Packing group		
ADR, IMDG, IATA	Not regulated	
14.5 Environmental hazards:		
Marine pollutant:	No	



• **14.6 Special precautions for user** Not applicable.

· 14.7 Transport in bulk according to Annex

II of Marpol and the IBC Code Not applicable.

· UN "Model Regulation": Not regulated

## SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Labelling according to Regulation (EC) No 1272/2008 Not applicable
- · Hazard pictograms No pictogram
- · Signal word No signal word
- · Hazard statements Not applicable
- · Other regulations, limitations and prohibitive regulations

Australia-AIIC: Listed China-IECSC: Listed Canada-DSL: Listed US-EPA TSCA: Listed EU-EINECS: Listed Taiwan-TCSI: Listed

Philippines-PICCS: Listed New Zealand-NZIoC: Listed Turkish Chemical Inventory: Listed Korea

KE-Number: KE-13703

Vietnam National Chemical Inventory (Draft): Listed

US-FDA - Color Additive Status List: Listed

Mexico - National Inventory of Chemical Substances: Listed

EU - Regulation No.1333/2008 - Part B - List of Food Additives: Listed Japan Food Sanitation Law - List of Designated Additives: Listed

- Substances of very high concern (SVHC) according to REACH, Article 57 the substance is not listed in current SVHC list.
- · 15.2 Chemical safety assessment:

Exposure assessment not required as substance is not classified as dangerous.



### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### · Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

ADR: Accord relatif au transport international des marchandises dangereuses par routé (European Agreement

Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative

#### Sources

REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labelling and packaging of substances and mixtures, amending and repealing COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No. 1907/2006

• Data from ECHA Dossier CAS 3844-45-9:

https://echa.europa.eu/registration-dossier/-/registered-dossier/20547/1

Data from Toxplanet:

https://chemical-search.toxplanet.com//product-search/listexpert/ei-fts-search/23c8fd7f-253f-4f59-b533-e01c500e7383

Data from Comptox:

https://comptox.epa.gov/dashboard/chemical/details/DTXSID2020189



- \* \* Data compared to the previous version altered.
   Section 1: Identification of the substance/mixture and of the company/undertaking
- Section 2: Hazard Identification
- Section 9: Physical and Chemical properties.
- Section 11: Toxicological Information.
- Section 12: Ecological Information